EXHIBIT 43

IR# S08-124, S08-129

UDL INTERNAL INVESTIGATION RECORD

PRODUCT NAME/DOSAGE FORM & STRENGTHS:	Digitek® (Digoxin Tablets USP) 125 mcg (0.125 mg) Digitek® (Digoxin Tablets USP) 250 mcg (0.25 mg)
MANUFACTURER:	Actavis Totowa LLC (formerly Amide Pharm., Inc.)
SUPPLIED BY:	Mylan Pharmaceuticals Inc.
LOT NUMBERS:	All UDL Lots (19) within expiry (EXHIBIT 1).
NDC NUMBERS / PACKAGE TYPE:	51079-945-20 (UD100) 125 mcg (0.125 mg) 51079-945-57 (UD300) 125 mcg (0.125 mg) 51079-945-56 (PC300) 125 mcg (0.125 mg) 51079-945-66 (CP180) 125 mcg (0.125 mg) 51079-946-20 (UD100) 250 mcg (0.25 mg) 51079-946-66 (CP180) 250 mcg (0.25 mg)
CLASSIFICATION:	CLASS 1 DRUG RECALL – NATIONWIDE VOLUNTARY RECALL INITIATED BY ACTAVIS
REASON:	The product is being recalled due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.
INVESITIGATION PLAN:	COMPLAINT HISTORY STOCK STATUS REVIEW RECEIVING INSPECTION RECORD REVIEW PACKAGING RECORD REVEIW RETENTION SAMPLE REVIEW STABILITY RECORDS/HISTORY REVIEW
ATTACHMENTS:	EXHIBIT 1 – UDL LOT NUMBERS EXHIBIT 2 – COMPLAINT HISTORY EXHIBIT 3 – BLISTER CAVITY DRAWINGS AND SPECIFICATIONS EXHIBIT 4 – BATCH RECORD REVIEW EXHIBIT 5 – EXAMINATION OF RETAIN SAMPLES EXHIBIT 6 – STABILITY RECORDS/HISTORY

EXHIBIT M69
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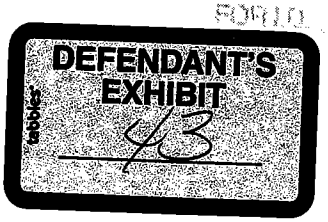

IR# S08-124, S08-129

INVESTIGATION SUMMARY:

Receiving Inspection Records - On 4/29/08, a review of the receiving inspection records for all Digitek lots was completed by QA. The QA Receiving Product Inspection records were examined and all lots demonstrated tablet thickness measurements within UDL product specification tolerances. The established thickness tolerances for Actavis and UDL are as follows:

Strength	Actavis	UDL
250 mcg	2.7mm to 3.7mm	3.15mm to 3.29mm
125 mcg	2.0mm to 3.0mm	2.58mm to 2.98mm

It should be noted that UDL's tolerances for creation of blister cavity size are tighter than the manufacturer's tolerances for thickness and UDL's maximum tolerance is used during the creation of the blister tooling. The depth of the blister tool is NMT 110% of the maximum tablet thickness; 0.36mm of maximum head space for 250 mcg and 0.30mm for 125mcg (EXHIBIT 3). There were no investigation reports generated during the receiving inspection related to tablet thickness.

Batch Record Documentation - On 4/29/08, a batch record review for each of the 19 UDL finished lots was completed by QA. During this review, a list that identifies each UDL finished lot number, manufacturer's lot number, UDL package configuration, tooling assignment and machine number was created (EXHIBIT 4). The QA In-Process Inspection records were examined for each lot and there were no machine issues or inspection observations related to tablet thickness. The lots met all in-process and finished goods inspection acceptance criteria for product release.

Examination of Retain Samples - On 4/30/08, a visual examination of retains for both strengths of Digitek was completed. Upon evaluating the fit of the tablets within the blister cavity, it was observed that both blister cavity sizes have minimal head space that would prevent tablets to be packaged with double the thickness. If the tablet thickness were to exceed the blister cavity size during packaging, visible damage to the blister package would occur and the equipment would experience a seal station overload (jamming within the seal station) that would result in a shutdown of the equipment. This type of occurrence is documented on the inspection record in the batch record. As stated above, there was no documentation in the batch record of a machine or inspection related issues involving tablet thickness.

Additionally, retains from four random lots of each strength (8 total) were measured by QA for tablet thickness. The 250 mcg tablets measured between 3.17mm and 3.27mm. The 125 mcg tablets measured between 2.69mm and 2.87mm. All tablets measured within the manufacturer's and UDL's tolerances for thickness (EXHIBIT 5).

IR# S08-124, S08-129

INVESTIGATION SUMMARY:

Complaint History – A review of all complaints received by UDL for Digitek, all strengths, beginning March of 2006 to present, was completed on 4/24/08 (EXHIBIT 2). There were no complaints in 2006 and 2007. In 2008, there were 33 complaints for the CP180 package only. CP180 is a new package that was designed and packaged specifically for Wal-Mart (retail compliance package). Out of the 33 complaints for CP180, 32 were specific to the customer's dissatisfaction with the package style (Shellpak). One complaint for Digitek 125 mcg (#08-038) reported that the customer observed that the tablets appear smaller than usual and that her heart was racing. This complaint was forwarded to PSRM on 3/18/08 for investigation and it remains open.

Stock Status - Stock status for all Digitek lots under UDL's control was examined on 4/24/08 and all remaining inventory was placed in Quarantine at UDL, or in Blocked Status at the Distribution Center (GSO), as follows:

UDL MRB LOCATION
125 mcg (0.125 mg), Actavis Lot 70953A1 - 216 Bottles of 5000
125 mcg (0.125 mg), Actavis Lot 80191A1 – 540 Bottles of 5000
125 mcg (0.125 mg), Actavis Lot 80192A1 – 540 Bottles of 5000
250 mcg (0.25 mg), Actavis Lot 80111A1 – 816 Bottles of 5000
250 mcg (0.25 mg), UDL Lot 8F684 – 1012 UD100
250 mcg (0.25 mg), UDL Lot 8A332 – 110 CP180

GSO QA HOLD LOCATION
125 mcg (0.125 mg), UDL Lot 8C515 - 4855 UD100
125 mcg (0.125 mg), UDL Lot 8C514 – 98 PC300
125 mcg (0.125 mg), UDL Lot 8B371 – 4684 CP180
250 mcg (0.25 mg), UDL Lot 7V200 – 59 UD100
250 mcg (0.25 mg), UDL Lot 8A332 – 4210 CP180

IR# S08-124, S08-129

INVESTIGATION SUMMARY:

Stability Records/History – On May 5, 2008, review of the stability data for Digitek 125 mcg and 250 mcg was completed by the UDL Stability Manager. According to the report, the product was introduced to the UDL product line in 2000. There are currently six active studies for 125 mcg and three for 250 mcg strengths. Additional active studies for the 125 mcg are due to it being packaged in additional packaging configurations. The product is tested for potency and dissolution. According to the records, the potency showed no apparent trending, but did show some variability at the later testing intervals. The dissolution testing did show variable testing results between intervals and several sporadic S2 dissolutions, but there is no apparent trend to the data. Overall, there is no-remarkable stability data through the assigned expiration date in the UDL unit dose package (EXHIBIT 6).

Conclusion - Records reviewed (receiving, tooling, packaging and stability), retain sample examination and complaint history for products and lots in question, demonstrate no evidence of unusual events that could be related to the packaging of double the thickness tablet in unit dose blisters.

UDL is continuing a voluntary Class I nationwide recall of the Actavis Totowa LLC recall of Digitek (all lots and strengths).

PREPARED BY: _____ **DATE:** 5-15-08

REVIEWED BY: Ilana Radtke **DATE:** 5-15-08